



300 DELAWARE AVENUE • SUITE 200 • WILMINGTON, DELAWARE 19801
TEL: (302) 472-7300 • FAX: (302) 472-7320 • WWW.HEGH.LAW

Direct Dial: (302) 472-7311
Email: dgattuso@hegh.law

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VIA ECF

The Honorable Leonard P. Stark
United States District Court
J. Caleb Boggs Federal Building
844 North King Street
Wilmington, DE 19801-3570

Re: *H. Lundbeck A/S, et al. v. Apotex Inc. et al.*, C.A. No. 18-088 (consolidated)

Dear Chief Judge Stark:

I write on behalf of Defendants Sandoz Inc. and Lek Pharmaceuticals d.d. (“Lek”) (collectively, “Sandoz Defendants”) in response to Plaintiffs’ request at the December 18, 2019 hearing that Sandoz Inc.’s counterclaims be dismissed *with* prejudice (Hr’g Tr. 90:10—91:15) in the event the Court grants the Sandoz Defendants’ Motion for Partial Judgment on the Pleadings under Fed. R. Civ. P. 12(c) and to Dismiss for Lack of Subject Matter Jurisdiction under Fed. R. Civ. P. 12(b)(1). (D.I. 415.) Plaintiffs first made this request at the December 18 hearing and thus it was not previously briefed by the parties. For the reasons explained below, if the Court grants the Sandoz Defendants’ motion, Sandoz Inc.’s counterclaims should be dismissed *without* prejudice – just as Plaintiffs’ claims would be dismissed without prejudice.¹

First, Sandoz Inc.’s counterclaims of non-infringement and invalidity for the crystal polymorph patents were made in response to Plaintiffs’ Complaint and are, in essence, a mirror-image of the claims in Plaintiffs’ Complaint. (D.I. 335, Ans. at 38-39 (Invalidity & Non-Infringement) & Counterclaims, ¶¶ 33-92.) Dismissing Plaintiffs’ claims *without* prejudice while dismissing Sandoz Inc.’s claims *with* prejudice would place the parties on a different legal footing and thereby unfairly prejudice Sandoz Inc. Plaintiffs have not identified any authority for treating the mirror-image counterclaims differently than Plaintiffs’ claims and the Sandoz Defendants are aware of none. Instead, the “law makes clear that dismissal with prejudice should rarely be used as a sanction” and that it is “reserved for those cases where there is a clear record of delay or contumacious conduct by plaintiff.” *Univ. of Pittsburgh v. Varian Med. Sys., Inc.*, 569 F.3d 1328, 1334 (Fed. Cir. 2009) (applying Third Circuit law). The Third Circuit applies the six *Poulis* factors when determining whether to dismiss with prejudice: “(1) the party’s personal responsibility; (2) the prejudice to the adversary; (3) a history of dilatoriness; (4) willfulness or bad faith; (5) the availability of alternate sanctions; and (6) the merit of the claim or defense.” *Bull v. U.S. Parcel Serv., Inc.*, 665 F.3d 68, 80 (3d Cir. 2012) (quoting *Poulis v. State Farm Fire & Cas. Co.*, 747 F.2d 863, 867 (3d Cir. 1984)). Plaintiffs never addressed the *Poulis* factors at the December 18 hearing, nor did

¹ Only one of the two Sandoz Defendants, Sandoz Inc., filed counterclaims and thus a dismissal with prejudice would preclude Sandoz Inc., but not Lek, from filing new counterclaims should Plaintiffs file a new suit at a later time.

they even allege “delay or contumacious conduct” by the Sandoz Defendants, so there is no basis for dismissing Sandoz Inc.’s counterclaims with prejudice.²

Second, dismissing an ANDA submitter’s counterclaims with prejudice would run contrary to public policy favoring declaratory judgment counterclaims, like Sandoz Inc.’s counterclaims, in patent suits. Mirror-image declaratory judgment counterclaims serve an important public policy of ensuring that, where the district court has already reached a question of patent validity, the appellate court will review that decision even if it also finds the patent not infringed, thus preventing what the Supreme Court has called the “wasteful consequences of relitigating the validity of a patent . . .” *Cardinal Chem. Co. v. Morton Int’l, Inc.*, 508 U.S. 100-01 (1993); *Nystrom v. Trex Co.*, 339 F.3d 1347, 1351 n.* (Fed. Cir. 2003). Granting Plaintiffs’ request to dismiss Sandoz Inc.’s counterclaims with prejudice would not only unfairly punish Sandoz Inc. in this case, it would discourage other ANDA submitters from filing counterclaims fearful of a dismissal with prejudice, which is contrary to the public’s interest in finality and efficient resolution of issues of patent validity.

Third, dismissing Sandoz Inc.’s counterclaims with prejudice would run counter to the purpose of the Hatch-Waxman Act in providing for 180-day exclusivity as a “special incentive for a generic to be a first to file an Abbreviated New Drug Application [(‘ANDA’)] taking the paragraph IV route.” *See Fed. Trade Comm’n v. Actavis, Inc.*, 133 S. Ct. 2223, 2228-29 (2013). Plaintiffs’ request for a dismissal of Sandoz Inc.’s counterclaims with prejudice seeks to penalize Sandoz Inc. for having done exactly what Congress intended it to do: file an ANDA with a Paragraph IV certification on the first possible date. Dismissing Sandoz Inc.’s counterclaims with prejudice would be particularly unfair here given the substantial changes in the patent landscape that occurred after Sandoz Inc. submitted its ANDA, e.g., its initial three-patent suit morphed into a consolidated thirteen-patent suit; and the two compound patents for which Sandoz Inc. has consistently maintained Paragraph III certifications received 1,354 days of patent term extension, pushing their expiration date from October 2, 2022 to June 17, 2026. (D.I. 416, Br. at 6-7.) If Hatch-Waxman counterclaims are dismissed with prejudice, there are several potential adverse consequences, including: (1) deterring future Paragraph IV challenges because ANDA filers fear a dismissal with prejudice, thereby delaying the introduction of lower-cost generic medications to the marketplace; and (2) increased litigation because ANDA filers can no longer withdraw from a litigation when the patent and competitive landscape changes substantially, as it did here.

² Indeed, applying the *Poullis* factors, Sandoz Inc.’s conduct does not rise anywhere near the type of “contumacious conduct” that could possibly warrant the “drastic sanction” of dismissal with prejudice. *See Univ. of Pittsburgh*, 569 F.3d at 1334. Sandoz Inc.’s responsibility is limited given that it submitted Paragraph IV certifications for the crystal polymorph patents and mirror-image counterclaims consistent with public policy favoring both. *See infra*, pp. 2-3. Plaintiffs are not prejudiced as they will have the ability to pursue new claims for infringement against the Sandoz Defendants and enjoy a new 30-month stay if Sandoz Inc. ever submits new Paragraph IV certifications for the crystal polymorph patents. Sandoz Inc. was not dilatory, but instead converted to Paragraph III in June 2019 – 1.5 years prior to the scheduled October 2020 trial date – and promptly notified Plaintiffs within days of the Paragraph III conversions. There is nothing to suggest bad faith by the Sandoz Defendants, which gain nothing from converting to Paragraph III; Sandoz Inc.’s conversion resulted in the irrevocable loss of its eligibility for 180-day exclusivity; relinquishment of its place in the U.S. Food & Drug Administration’s queue for approval; and incurrence of a new 30-month stay should it change course. Nor was this an instance where the Sandoz Defendants’ decision was based on the lack of meritorious defenses. For example, the Sandoz Defendants’ invalidity defenses are spelled out in contentions that the other defendants are continuing to pursue. If Plaintiffs belatedly attempt to establish the existence of the *Poullis* factors, the Sandoz Defendants respectfully request an opportunity to submit full briefing to the Court.

Finally, the law does not support dismissing Sandoz’s Inc.’s counterclaims with prejudice where the allegations in the complaint are dismissed under either Fed. R. Civ. P. 12(b)(1) and 12(c). If the Court is inclined to grant the Sandoz Defendants’ motion to dismiss on the basis of lack of subject matter jurisdiction under Fed. R. Civ. P. 12(b)(1), dismissal of Sandoz Inc.’s counterclaims with prejudice would be improper because it is well-established that “a lack of subject matter jurisdiction usually justifies only a dismissal, not a dismissal with prejudice.” *Textile Prods. v. Mead Corp.*, 134 F.3d 1481, 1486 (Fed. Cir. 1998); *Crotwell v. Hockman-Lewis, Ltd.*, 734 F.2d 767, 769 (11th Cir. 1984) (holding that “[s]ince the court lacked subject matter jurisdiction over the action, it had no power to render a judgment on the merits” and therefore erred in dismissing with prejudice). Sandoz Inc.’s 12(c) motion seeks dismissal without prejudice because the required artificial act of infringement under 35 U.S.C. § 271(e)(2) no longer exists – not judgment on the merits of Sandoz Inc.’s non-infringement and invalidity defenses. Because no judgment on the merits is at stake, dismissal with prejudice under 12(c) is inappropriate.

Respectfully,

/s/ *Dominick T. Gattuso*

Dominick T. Gattuso (#3630)

cc: All Counsel of Record Via Electronic Mail